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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER, INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. Member companies are the source of a majority of all new medicines that are discovered and marketed. New medicines accounted for 40 percent of the lifespan increase between 1986 and 2000. *See* Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, 21 (Nat'l Bureau of Econ. Research, Working Paper No. 9754, 2003). In the past decade alone, PhRMA's members invested approximately $300 billion to develop new medicines. *See* PhRMA, *Pharmaceutical Industry Profile 2007* 42 (2007).

PhRMA's members closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues. PhRMA has a particular interest in cases involving possible state-law interference with the comprehensive public health regulatory regime for prescription drugs administered

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1. Pursuant to Rule 37.1 of the Rules of the Supreme Court of the United States, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

by the Food and Drug Administration ("FDA"). PhRMA supports and endorses this Court's safeguarding of the "inherently federal" relationship between FDA and pharmaceutical manufacturers against state law intrusion based on alleged fraud on the FDA, *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and submitted a brief *amicus curiae* supporting the grant of certiorari in this case. *See* Brief of the Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Petitioners, Warner-Lambert Co. v. Kent, No. 06-1498 (filed July 20, 2007). PhRMA strongly believes that the Second Circuit's decision was flawed in several respects and asks that this Court reverse the judgment of the court below under the reasoning of its decision in *Buckman*.

INTRODUCTION

In *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court held that state law claims that authorized recovery against medical device and drug manufacturers where regulatory approval was allegedly procured through "fraud on the FDA" were preempted. The court below, however, upheld a "fraud on the FDA" claim framed as an exception to a Michigan affirmative defense that otherwise insulated FDA-approved drugs from product liability claims. The decision below cannot be squared with this Court's precedent and, if allowed to stand, would evade *Buckman*'s bar on state-law interference in the manufacturer-FDA relationship through only slightly more subtle means. The likely proliferation of state-law fraud on federal regulators litigation and the resulting interference with congressionally granted federal authority that would follow would significantly burden both the health care and judicial systems.

The Second Circuit ruled that because Respondents' causes of action were not grounded *solely* on a fraud-on-the-FDA theory, *Buckman* did not control. The court sought to bolster that contention by characterizing it as the position "the pharmaceutical industry" took in *Buckman*. The court was wrong on both counts. The conflict that drove this Court's preemption decision in *Buckman* arose from the state's assertion of power to review the regularity of FDA approvals under state law, not from the specific role that such review played in state litigation. The industry's position then, as now, is that such review would frustrate the objects and purposes of federal law and cannot be sustained under the Supremacy Clause. Thus, as in *Buckman*, liability here turns on Respondents' ability to prove as a matter of *state law* that Petitioners' FDA approval was obtained through fraud on the FDA. Allowing judges and juries to determine that issue would produce the same interference with FDA's regulatory mandate that led this Court to preempt fraud on the FDA actions in *Buckman*. That the Michigan statute uses the resolution of that question as a means of overcoming an otherwise available product liability defense cannot justify it constitutionally.

In addition, to shore up its faulty interpretation of *Buckman*, the Second Circuit wrongly invoked a "presumption against preemption." The presumption, which is of dubious constitutional heritage generally, has absolutely no place in conflict preemption cases where the rule of decision is provided by Article VI of the Constitution-not, as in express preemption cases, by an Act of Congress. Furthermore, the fact that the Michigan "legislative scheme" addresses product liability does not, as the Second Circuit asserted, alter this conclusion;

indeed, the claims in *Buckman* were allegedly framed within the States' traditional areas of tort action. States cannot obtain the benefit of the presumption by burying interference with an area of traditional federal control in an exception to an affirmative defense. The need to establish fraud on the FDA in order to obtain relief under state law rendered the presumption inapplicable in *Buckman*, and so it does here.

The Second Circuit also ignored the adverse practical consequences of allowing state-law "fraud on the FDA" to be litigated in case after case. Permitting this uniquely federal question to be incorporated into state law would defeat Congress's deliberate decision to grant FDA ample and exclusive authority to establish information filing requirements and police fraud on the agency. The interference that would necessarily flow from state "fraud on the FDA" litigation would disrupt FDA's ability to accomplish the tasks assigned to it by Congress.

State superintendence of "fraud on the FDA," moreover, expressly invites state-law courts to second-guess FDA approval determinations. Michigan permits juries to determine for themselves, under state law, whether (1) there was a fraudulent misrepresentation or omission and (2) if that "fraud" would have led FDA to prevent the product from coming to market or remove an approved product from the market. These highly scientific and technical judgments have been delegated by Congress to an expert agency for a reason. Congress understood that judges and juries facing an injured plaintiff in a single case were not in a position to make complex scientific decisions with consequences that could

have a significant effect on public health for millions of Americans. FDA's expertise and judgment in this area, therefore, has always been entitled to considerable deference-deference that would be denied the agency under the Second Circuit's mistaken rationale.

Upholding the Second Circuit's decision could induce PhRMA's members to adopt a decidedly defensive posture before FDA. Uncertainty as to the scope of potential tort exposure for non-disclosure under state law would create an incentive for drug manufacturers to inundate FDA with information in an effort to ensure that they were not charged with "fraud" under state law for omitting from their approval applications information that a judge or jury later might find "material" to FDA's approval decision. Indeed, manufacturers would be compelled to make such submissions even if FDA expressed no interest in receiving the information since the agency would not be the ultimate arbiter of the fraud question. Manufacturers also would have reason to demand, in order to document these prophylactic submissions, formal and detailed responses from FDA. As explained in *Buckman*, a flood of filings would strain FDA's resources, restrict the agency's ability to effectively balance drug safety and efficacy, and generally undermine the inherently federal FDA-manufacturer relationship.

These constitutional and practical concerns led this Court to conclude in *Buckman* that any state law that required courts to adjudicate "fraud on the FDA" wrongly intruded into an inherently federal relationship

and created an obstacle to the accomplishment of Congress's objectives in the FDA approval process. The Michigan exception requires judges and juries to determine, as a matter of state law, whether FDA approval was procured through fraud. Only if the answer is yes may the case proceed. The Second Circuit's attempt to distinguish this reliance on fraud on the FDA for state remedy administration from the reliance confronted by the Court in *Buckman* utterly fails. For all of these reasons, PhRMA respectfully requests that the Court reverse the decision below.

ARGUMENT

I. *BUCKMAN* REQUIRES PREEMPTION OF THE "FRAUD ON THE FDA" EXCEPTION TO THE MICHIGAN STATUTORY DEFENSE.

A. The Michigan Exception Would Obstruct FDA's Supervision Of Federal Disclosure Requirements In The Same Way As The "Fraud On The FDA" Claim Struck Down In *Buckman*.

The case at bar presented the Second Circuit with a product liability claim against a pharmaceutical manufacturer under Michigan law. *See Desiano v. Warner-Lambert Co.*, 467 F.3d 85, 93 (2d Cir. 2006). Michigan law provides pharmaceutical manufacturers a complete defense against a product liability claim so long as the product at issue is distributed in accordance with FDA rules and regulations. *See* Mich. Comp. Laws § 600.2946(5). The Michigan affirmative defense does not apply, however, if the manufacturer commits material

fraud on the FDA. *See id.* § 600.2946(5)(a) ("This subsection does not apply" if the manufacturer "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted . . . and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted.").

The constitutional viability of this "fraud-on-the-FDA" exception to the Michigan statutory defense depends on the force and meaning of this Court's decision in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the plaintiffs brought state-law causes of action, alleging that a consultant to a medical device manufacturer had made "fraudulent representations" to FDA during the approval process. *See id.* at 343. According to the plaintiffs, "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id.* This Court unanimously ruled that this state-law "fraud-on-the-FDA" claim conflicted with, and "therefore [was] impliedly pre-empted by, federal law." *Id.* at 348; *see also id.* at 353 n.1 (Stevens, J., concurring) (agreeing that "federal law 'pre-empts' this state-law fraud-on-the-FDA claim").

As this Court then explained, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. The federal regime could not properly function "in the shadow of 50 States' tort regimes." *Id.* at 350. Indeed, allowing judges and juries to determine under state law

whether "fraud on the FDA" had occurred would "cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351. Manufacturers therefore would be prompted to "submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Id.*

In the present case, even though Respondent's ability to recover for product liability under Michigan law also turns on a finding that Petitioners procured FDA approval through fraud, the Second Circuit rejected the applicability of *Buckman* and ruled that the exception to the Michigan statutory defense was not preempted. *See Desiano*, 467 F.3d at 93 (finding a "meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law"); *see also id.* at 94-95 (stating that, in contrast to *Buckman*, none of the claims "derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency"); *id.* at 95 (distinguishing *Buckman* because, in that case, "there were no free standing allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements"). As explained below, the Second Circuit's justifications for distinguishing *Buckman* do not pass muster. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) ("Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*.").

The Second Circuit's central premise was that, unlike in *Buckman*, Respondents' legal claims were not "solely" grounded on a "fraud on the FDA" theory. *See Desiano*, 467 F.3d at 95 (concluding that "unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA" and that "plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime"). Setting aside whether the distinction drawn by the Second Circuit is accurate, it is without a doubt immaterial. This Court's preemption decision in *Buckman* did not turn on whether fraud on the FDA was alone sufficient to trigger liability under state law. Indeed, the parameters of the state law at issue in *Buckman* were not clearly defined, and it is far from certain that a finding of fraud on the FDA would alone have been sufficient to impose liability on the defendant in that case. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 822 (3d Cir. 1998), *rev'd, sub nom. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) ("While it is clear that the plaintiffs' 'fraud on the FDA' claims are based on state rather than federal law, . . . the controlling state law of fraudulent representation in some cases may be different from that in other cases."). Rather, it was the consequences of allowing a plaintiff to prove as a matter of state law that the manufacturer had wrongly obtained FDA approval either by making affirmative misrepresentations or by withholding information from the agency that drove the decision in *Buckman*. *See id.* (explaining that the claim in *Buckman* was "drafted to track the elements of a common law cause of action for fraudulent misrepresentation") (citing Restatement (Second) of Torts § 525 *et seq.*); *see also Buckman*, 531 U.S. at 346-

47 (noting the claims at issue were "state-law causes of action claiming that petitioner and AcroMed made fraudulent representations to the FDA . . . and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detriment"). On this ground, the case at bar and *Buckman* are indistinguishable.

In fact, none of the reasons articulated for finding preemptive conflict in *Buckman* depended in any way on the fact that the alleged fraud on the FDA was a stand-alone claim. *See id.* at 348 ("The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud."). Instead, the Court preempted the state-law cause of action because "the existence of these federal enactments [was] a critical element in [the plaintiffs'] case," *id.* at 353, and, accordingly, any state-law claim that interfered with the inherently federal relationship between regulated manufacturers and the FDA was foreclosed. *See id.* at 350 (explaining that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA"); *id.* at 351 ("[F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court.").

Here, just as in *Buckman*, liability under state law turns on whether the plaintiff can establish that Petitioners obtained FDA approval through fraud. *See Desiano*, 467 F.3d at 95. Michigan law unquestionably

forces courts to inquire into whether the manufacturer intentionally withheld from or misrepresented required disclosures to the FDA and whether that omission or misrepresentation would have altered FDA's decision to allow the drug to enter or remain on the market. *See* Mich. Comp. Laws § 600.2946(5)(a). This is the precise inquiry that was preempted in *Buckman*. *See Garcia*, 385 F.3d at 965-66 (recognizing that, although the Michigan statute "presents a somewhat different legal regime from the one invalidated in *Buckman*," the "difference . . . is immaterial in light of *Buckman*"); *see also Ledbetter v. Merck & Co.*, Nos. 05-59499 & 05-58543, 2007 WL 1181991 (Tex. Dist. Ct. Harris County Apr. 19, 2007) ("Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply."); *Henderson v. Merck & Co.*, No. 04-CV-05987, 2005 WL 2600220, at *11 (E.D. Pa. Oct. 11, 2005) ("This Court follows the holdings of *Buckman* and *Garcia*, and finds that . . . [Sections] 600.2946(5)(a) and (b) are preempted by the FDCA in most situations.").[2]

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2. Michigan law is clear that, when claiming an exception to an affirmative defense, the burden lies with the plaintiff to show all of the elements of fraud on the agency, and it is properly considered a "claim" that the plaintiff must make. *See Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003); *Feyz v. Mercy Memorial Hosp.*, 719 N.W.2d 1, 10 n.45 (Mich. 2006); *McNeil ex rel. McNeil v. Metinko*, Nos. 194595 & 194596, 1998 WL 2016585, at *1 (Mich. Ct. App. March 13, 1998). The Second Circuit's conclusion that the alleged fraud on the FDA will be raised based on a defendant's invocation of the statutory affirmative defense and "that it is not up to the plaintiff to prove

(Cont'd)

To bolster its faulty reading of *Buckman*, the Second Circuit announced that its conclusion was not different from "the position the pharmaceutical industry articulated at oral argument in *Buckman*." *Desiano*, 467 F.3d at 95. In particular, the court relied on a statement made by Buckman's counsel: "The plaintiffs don't claim that these devices were in any way defective. . . . Instead, the plaintiffs' sole claim in this case is the following. They assert that the Federal Food & Drug Administration was deceived into giving regulatory clearance to these devices." *Id.* at 95-96 (quoting Oral Argument Transcript, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 2000 WL 1801621 (2000) (No. 98-1768) (hereafter "*Buckman* Transcript")); *see also id.* at 96 n.8 (concluding that "a second lawyer for the industry indicated that traditional tort remedies were *not* implicated by *Buckman*" because "[w]hen asked about what remedies an injured plaintiff would have under his theory of the case, the attorney responded: 'The *fraud* claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available[.]'") (quoting *Buckman* Transcript at *21).

These statements should not have been attributed to the "pharmaceutical industry"; they were instead advanced by the Petitioner in *Buckman*-a consulting

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(Cont'd)
fraud as an element of his or her claim," *see Desiano v. Warner-Lambert Co.* 467 F.3d 85, 96 (2d Cir. 2006), thus coyly, but unsuccessfully, sidesteps the dispositive question—*i.e.*, which party bears the ultimate burden of proof. The Second Circuit did not—and could not—dispute that the ultimate fraud burden resides with the plaintiff under Michigan law.

company for medical device manufacturers-and by the United States government. *See id.* at 95; *Buckman* Transcript at *3-4, 21. PhRMA, which does represent "the pharmaceutical industry," in fact filed an *amicus curiae* brief in *Buckman*. *See* Brief of the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Petitioner, Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2000) (No. 98-1768). The positions taken in that brief are in complete accord with the position taken here. *See id.* at 6 (explaining that federal law "require[d] preemption of state-law standards that permit[ted] the states to scrutinize the FDA approval process and second-guess the validity of FDA approval determinations" and that "[t]hese standards, whether imposed through common-law causes of action or statutory schemes, would impermissibly disrupt the intended uniformity and certainty of the federal approval regime, and could lead to reduced availability of important medical products"); *id.* at 14 (taking the position that "[t]he integrity of the FDA approval regime requires preemption of state-law standards-including respondents' 'fraud on the FDA' claims-that permit ad hoc (or systematic) challenges to the validity of FDA approval decisions").

Moreover, the Second Circuit completely mischaracterizes the arguments advanced by Buckman's counsel at oral argument. Counsel stated that "the plaintiffs' sole claim" was fraud on the FDA and that the plaintiffs did not claim that the devices were defective. *Buckman* Transcript at *3-4. Counsel did not argue that these distinctions were in any way material to the question before the Court, and certainly did not suggest that the case should come out any differently if

fraud on the FDA were only one part of a claim or a "necessary proof" element of a case. That issue was not before the Court, and the *Buckman* Petitioner would have had no reason to draw such a distinction. Indeed, portions of the argument before the Court omitted from the Second Circuit's discussion of this issue make clear that Buckman's position would have been the same even if the claim at issue was not based "solely" on fraud on the FDA:

> So this lawsuit is, in other words, a direct attack under State law on the decision of the Federal Food & Drug Administration[.] . . . [I]t means that a jury applying State law would have to decide such issues as, what sorts of disclosures have to be made to the Food & Drug Administration[?] What did the FDA know[?] Was the FDA deceived in any way in granting regulatory clearance?

Buckman Transcript at *4; *see also id.* at *9 ("[T]he point that I was simply making is the sorts of inquiries that a State judge or jury would have to make if this State law claim were allowed to proceed are inquiries that would delve heavily into the intricacies of the Federal regulatory process[.]").

Moreover, the United States, arguing in support of the Petitioner in *Buckman*, articulated exactly the point being made by the Petitioner and by PhRMA here: "[I]nsofar as they would be asserting an essential element of the claim . . . that the FDA was defrauded, that is an area of exclusive Federal concern, and the State common law cause of action would be preempted."

Id. at *21. Put simply, the record does not support any contention that the pharmaceutical industry conceded in *Buckman* the validity of a law such as the one at issue here. The Second Circuit's contrary makeweight is unsustainable.

B. The Second Circuit Erred In Applying A Presumption Against Preemption In This Case.

This Court, at times, has endorsed a "presumption against preemption" under which the review of a federal statute "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, (1947); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523-24 (1992) ("[W]e must fairly but-in light of the strong presumption against pre-emption-narrowly construe the precise language of § 5(b) and we must look to each of petitioner's common-law claims to determine whether it is in fact pre-empted."). The court below found that a presumption against preemption applied in this case. *See Desiano*, 467 F.3d at 93 ("[T]he presumption against federal preempt-ion of state law obtains in the case before us."). The Second Circuit's invocation of a "presumption" in the case at a bar was deeply flawed for at least two reasons.

First, a presumption against preemption has no legitimate role in conflict preemption cases. When Congress exercises its Article I power to occupy an area of commerce, or to foreclose state activity in a traditional area of state concern, without regard to a conflict of commands or purposes, principles of federalism might

properly counsel requiring a clear legislative articulation of the bounds of that foreclosure. *See, e.g., De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 813-14 (1997) (invoking a "presumption against preemption" to determine "the scope of the state law that Congress understood would survive" (citations and internal quotations omitted)); *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963) (explaining that the "principle to be derived from" past Supreme Court "decisions is that federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons-either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained."). That invocation of the "presumption" essentially supplies guidance in cases where it is unclear whether Congress intended to trump state law by positive enactment. *See, e.g., Cipollone*, 505 U.S. at 518 ("This presumption reinforces the appropriateness of a narrow reading of § 5.").

Where, however, the exercise of state authority would impose duties inconsistent with federal mandates or obstruct the objects and purposes of federal law, preemption arises directly from Article VI of the Constitution. The relevant Congressional intent relates to how Congress expects the federal regime to operate-an issue to which the presumption has no relevance. *See Chicago & Nw. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (explaining that conflict preemption analysis entails "essentially a two-step process of first ascertaining the construction of the two statutes and then determining the constitutional question whether they are in conflict") (citations and

quotations omitted); *Fla. Lime*, 373 U.S. at 142-43 ("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce."). Thus, for example, this Court determined the objects of National Highway Traffic Safety Administration's passive restraint regulation without regard to any presumption. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874-75 (2000) ("In a word, ordinary pre-emption principles, grounded in longstanding precedent apply." (internal citation omitted)). Having given appropriate deference to the operation of the federal regimes, the Court properly secured them from state interference. *See id.* at 875-86.

As this Court explained, if "the state law regulates conduct that is actually protected by federal law . . . pre-emption follows not as a matter of protecting primary jurisdiction, but as a matter of substantive right." *Brown v. Hotel & Rest. Employees and Bartenders Int'l Union Local 54*, 468 U.S. 491, 503 (1984). In this context, unlike with respect to Congressional preemption by exclusion, any substantive federalism concerns were resolved when the Framers chose to make federal law supreme. *See id.* at 503 (explaining that when "the issue is one of an asserted substantive conflict with a federal enactment, then '[t]he relative importance to the State of its own law is not material . . . for the Framers of our Constitution provided that the federal law must prevail'") (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)); *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) (explaining that under the Supremacy Clause "[t]he relative importance to the State of its own law is not

definition more difficult in implied preemption cases, where Congress has not codified its intent expressly. But it is most difficult in "obstacle" or "frustration of purpose" cases, which often arise under broad congressional mandates ordering administrative agencies to set minimum safety standards or labeling requirements.[23] In this context, neither the statutes nor their legislative histories provide much – if any – useful evidence regarding congressional intent on preemption. In such cases, courts must undertake the difficult task of attempting to discern the "full purposes and objectives" embodied in a statute or even a *regulatory framework* that does not speak directly to the issue of preemption – a controversial inquiry in which judges have scant guidance. And even if it were possible to ascertain the full purposes of a law or regulation, this Court has recognized that no law is intended to pursue its purposes at all costs.[24] Thus,

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Malone, 435 U.S. 497 at 504)); *see also English*, 496 U.S. at 78-79 ("Preemption fundamentally is a question of congressional intent. . . ."); *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996) (stating that the question of preemption "is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exercise its constitutionally delegated authority to set aside the laws of a State?").

[23] *See, e.g.*, *Bates*, 544 U.S. 431; *Sprietsma*, 537 U.S. 51; *Geier*, 529 U.S. 861.

[24] *See, e.g.*, *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646-47 (1990) (quoting *Rodriguez*, 480 U.S. at 525-26 ("[N]o legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice – *and it frustrates rather than effectuates*

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even in a case where a court is able to ascertain the federal purposes underlying a particular statute or regulation, notwithstanding the absence of an express congressional command, the question whether those purposes would be so deeply undermined by state tort law as to require the obliteration of victims' rights to seek compensation for their injuries requires a delicate inquiry that risks undermining the core federalism principles on which this country was based.

The broad range of potential intentions regarding a law's potential costs – including the obliteration of state law through preemption – only counsels further in favor of the presumption.[25] Courts have little basis on which to discern whether statutes or regulations that do not speak to preemption were intended to supplement state law, to preempt state law, or neither, and they lack the expertise to determine what would be best as a matter of policy. Apparently recognizing this problem, this Court's most recent decisions properly rejected arguments that statutes and regulations preempt state tort law absent clear evidence of a direct conflict with federal purposes. *See Bates*, 544 U.S. at 449-51; *Sprietsma*, 537 U.S. at 64, 65.

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legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law.") (emphasis added)).

[25] *See, e.g.*, Frank H. Easterbrook, *Statutes' Domains*, 50 U. CHI. L. REV. 533, 548 (1983) ("[J]udicial predictions of how the legislature would have decided issues it did not in fact decide are bound to be little more than wild guesses. . . .").

The vital importance of the presumption against preemption is underscored by another recent development: Federal agencies have embarked on an unprecedented attempt to influence the courts by voicing positions on preemption either in litigation or in preambles to regulations.[26] In many cases – particularly where the agency has previously argued that state law is *not* inconsistent with federal purposes (and thus is not preempted) – these positions are demonstrably unstable and politicized, therefore failing to represent the faithful, considered interpretation of congressional intent and regulatory needs.[27] For example, in *Bates*, this Court rejected preemption arguments by the Solicitor General that flatly contradicted the EPA's position in the California Supreme

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[26] *See generally* William Funk, et al., *The Truth About Torts: Using Agency Preemption to Undercut Consumer Health and Safety*, White Paper No. 704, at 6-9 (2007), *available at* http://www.progressivereform.org/articles/Truth_Torts_704.pdf.

[27] *See, e.g.*, Vladeck, 33 PEPP. L. REV. at 123 ("There is no dispute that the FDA's new position on the scope of the MDA preemption provision represents a 180-degree shift of position for the agency."). It is also unclear that administrative agencies have the authority to speak directly to preemption unless Congress has granted them that authority, and further unclear that Congress can grant them that authority without violating the separation of powers under the Constitution. *See, e.g.*, Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 331 (2000) (arguing that congressional rather than administrative decision making on preemption is "an important requirement in light of the various safeguards against cavalier disregard of state interests created by the system of state representation in Congress").

Court just four years earlier. *See* 544 U.S. at 437 & n.7; *id.* at 448-49 (rejecting Solicitor General's arguments as "particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."). The ubiquity of these new regulatory preemption efforts – which have occurred across numerous agencies and subject matters, without regard to whether Congress has altered the underlying statutes[28] – evidences a broad program of preemption by the executive branch that has nothing to do with congressional intent – and often directly undermines it. The presumption against preemption helps to ensure that courts will not rely on these or other improper arguments for the expansion of federal authority by instructing them to find preemption only when it is the "clear and manifest" intent of Congress.

For all of these reasons, the doctrine of "obstacle" or "frustration of purpose" preemption is fraught with potential for improper expansions of federal power and curtailment of the states' historic power to protect their citizens. The presumption against preemption serves as a crucial counterweight.

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[28] *See generally* Funk et al., *The Truth About Torts*, at 6-9.

B. The Chamber of Commerce's Policy Arguments Against the Presumption Are Overreaching and Unpersuasive.

1. The Chamber's claim that the presumption is not supported by federalism concerns, *see* Chamber Br. 6, 15-16, contradicts this country's core political values and the consistent teachings of this Court. For the reasons discussed above, the presumption against preemption is grounded in sound federalism policy dating back hundreds of years. In contending the opposite, the Chamber relies on a handful of law review articles and selective quotes from opinions that actually *support* the presumption. For example, the Chamber quotes *DeCanas v. Bica*, 424 U.S. 351 (1976), for the proposition that "even state regulation designed to protect vital state interests must give way to paramount federal legislation." Chamber Br. 16 (citing 424 U.S. at 357). But the very next sentences in that case reaffirm the presumption, stating, "[b]ut we will not presume that Congress . . . intended to oust state authority. . . . Only a demonstration that complete ouster of state power including . . . laws not in conflict with federal laws was 'the clear and manifest purpose of Congress' would justify that conclusion." 424 U.S. at 357. Indeed, *DeCanas* endorses perhaps the strongest form of the presumption, stating that "the proper approach is to reconcile 'the operation of both statutory schemes with one

another rather than holding (the state scheme) completely ousted.'" *Id.* at 358 (citation omitted).[29]

The Chamber engages in similarly selective reading of the commentators. For example, it relies heavily on Professor Caleb Nelson's argument against the presumption. *See* Chamber Br. 17, 19 (citing Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 293, 238-44, 254-60, 300, 302 (2000)). But it does not mention that Professor Nelson's argument addresses *express* preemption. *Id.* at 293-94. Even more telling, the Chamber fails to note that Professor Nelson rejects the doctrine of "obstacle" preemption outright, *id.* at 265-90 – a position that would compel resounding defeat for the petitioner here.

2. The Chamber also argues that the presumption is unnecessary in implied conflict cases because, in such cases, courts need only determine the "substance" of a federal statute – which the Chamber believes has nothing to do with preemption – and then determine whether the substance of federal law

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[29] The Chamber also relies on a dissenting opinion that endorses the presumption, disputing only whether it should apply to questions regarding the *scope* of express preemption provisions. *Compare* Chamber Br. 14 (citing *Cipollone*, 505 U.S. at 544 (Scalia, J.) [*sic*]) *with Cipollone*, 505 U.S. at 545 (Scalia, J., dissenting) (endorsing the "traditional principles" of preemption, which include the requirement that congressional intent to preempt be "clear and manifest," then critiquing the majority's use of the presumption not to determine whether an express preemption is preemptive, but rather to determine the *scope* of the provision).

conflicts with state law. In the Chamber's view, this inquiry is different from those regarding field or express preemption questions because it does not require discerning congressional intent. The Chamber is deeply mistaken.

In reality, discerning congressional intent is as important in implied conflict cases as it is in all other preemption cases, for congressional intent is the "touchstone" of preemption.[30] The major difference between express and implied preemption cases is that intent is much more difficult to discern in the latter – providing only a stronger justification for the presumption.[31]

The Chamber is also mistaken in believing that the "substance" of federal laws can be disentangled easily from their preemptive effect. There is a vast difference between a federal regulatory regime that sets a minimum safety standard and is silently intended to be supplemented by tort litigation and one that sets both a "floor" and a "ceiling" with regard to safety and is silently intended to displace tort law, leaving all injured victims with no compensation. This difference is surely one of "substance," yet it also goes to the core of the preemption analysis. Put another way, a federal law may be intended to incorporate state law; to be supplemented by state law without incorporating it; to operate without

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[30] *Cipollone*, 505 U.S. at 516.

[31] *See supra* § II.A.

preemption even when superceded by state law; to preempt only conflicting state law; or to preempt all state law in the area. To call these aspects of a law something other than "substance" is to engage in little more than wordplay.[32] In effect, the Chamber's proposed preemption framework improperly assumes away the question, for it omits the possibility that Congress might have intended to incorporate, accommodate, or leave state law undisturbed.[33]

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[32] Countless federal provisions could be labeled either "substantive" or "preemptive." Professor Nelson explains, for example, that the Supreme Court has labeled "substantive" § 2 of the Federal Arbitration Act, 9 U.S.C. § 2 (2008), which states that a written arbitration agreement in a "contract evidencing a transaction involving commerce" shall be "valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract." *See Southland Corp. v. Keating*, 465 U.S. 1, 15 n.9 (1984). But one could draft a nearly identical express preemption provision, stating that "no state or local government shall adopt or enforce any law or policy that makes a written arbitration agreement in a contract evidencing a transaction involving commerce invalid, revocable, or unenforceable, save upon such grounds as exist at law or in equity for the revocation of any contract." Nelson, 86 VA. L. REV. at 299.

[33] Indeed, the Chamber attempts to support this argument primarily by citing a case that did not even decide a preemption question. *See* Chamber Br. 18, 19 (citing *Smiley*, 517 U.S. at 744). *Smiley* explained that the question whether the statute at issue was preemptive had been decided long ago, in *Marquette National Bank of Minneapolis v. First of Omaha Service Corp.*, 439 U.S. 299 (1978). Therefore, the Court explained, *Smiley* itself concerned only the substantive meaning of the statute – in particular, the definition of the term "interest." *See* 517 U.S. at 744. In light of the Comptroller of the Currency's regulation on

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3. Finally, it is noteworthy that the Chamber's arguments apply not just to implied conflict preemption, but to all preemption cases. Its sweeping dismissal of "the free-form concept 'federalism concerns,'" Chamber Br. 6; *see also id.* 15-16, cannot be limited to implied conflict cases. If federalism is insufficient justification for applying the presumption in implied conflict cases, where Congress has not even made its intentions clear, then states' rights should be accorded even less respect in cases where Congress has exerted federal power more clearly. Similarly, the Chamber's argument that courts should abandon the presumption and instead simply read the substance of federal law, and then call conflicts as they see them, applies *more* readily to express and field preemption than to implied conflict preemption. (Regarding express preemption, the logical outgrowth of the Chamber's argument is that there is no need for a presumption because the intent of Congress is explicit, and therefore courts should read its words without biasing the inquiry.[34] Regarding field preemption, the argument would be that there is no need for a presumption because courts need only discern the content of federal

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the matter, the Court answered this question with an ordinary *Chevron* analysis. *Id.* at 744-45.

[34] This type of strict-construction argument of course carries the corollary that there should be *no* "obstacle" preemption, which by definition entails finding preemption from sources other than the text of statutes or regulations. *See, e.g.*, Nelson, 86 VA. L. REV. at 265-90.

law to determine the "field" it covers, and then hold that any conflicting state law is void.)

That the Chamber's argument for jettisoning the presumption against preemption applies to all preemption cases may be unsurprising given the malleability of preemption categories. *See supra* n.5. But it is noteworthy, for it reveals the astonishing breadth and novelty of the Chamber's position. Although the Chamber claims to challenge the presumption merely in implied conflict cases, its arguments inevitably amount to an attack on the presumption in *all* preemption cases – an argument wildy divergent from this nation's long-established law and values. In essence, the Chamber advocates federal judicial overreaching that would dramatically frustrate democratic governance and uproot the states' historic power to protect the health and safety of their citizens. These arguments should be rejected.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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